## REMARKS

This Amendment and Response is being submitted concurrently with a Petition to Revive an Unintentionally Abandoned Application Under 37 C.F.R. § 1.137(b). This Amendment and Response constitutes the reply required to the outstanding Office action or notice pursuant to 37 C.F.R. § 1.137(b)(1).

Claims 1-49 are pending in the above-identified patent application and are under consideration.

The specification was objected to as containing sequence disclosures that failed to comply with the requirements for 37 C.F.R. §§ 1.821-1.825. Sequence identifiers were not given, a written copy of the sequence listing was not submitted, and a computer readable form of the sequence listing was not submitted.

Claims 2, 18, and 38 were objected to because of informalities; specifically, the claims used brackets in reciting the names of chemical compounds.

Claims 14, 30, and 45 were objected to under 37 C.F.R. § 1.75(c) as being of improper dependent form for failing to further limit the subject matter of a previous claim.

Claims 5, 9, 14, 21, 25, 30, 32-35, 41, 44, 46, and 48 were rejected under the second paragraph of 35 U.S.C. § 112 for indefiniteness.

Claims 1-8, 14-15, 17-24, 30, 36-43, 45-46, and 48 were rejected under 35 U.S.C. § 102(b) as anticipated by C.H. Chung et al., "An Improved Method for Isolating High Quality Polysaccharide-Free RNA from Tenacious Plant Tissues," Mol. & Cells 6: 108-111 (1996) ("Chung et al. (1996")).

Claims 1-6, 8-9, 14-22, 24-25, 30-41, and 43-48 were rejected under 35 U.S.C. § 102(b) as anticipated by PCT Published Patent Application No. WO 93/03167 by Sigman et al. ("Sigman et al. '167").

Claims 1-6, 8-9, 14-16, 37-41, and 43-47 were rejected under 35 U.S.C. § 102(b) as anticipated by PCT Published Patent Application No. WO 95/35390 by Zhang ("Zhang '390").

Claims 1-3, 6, 10-19, 22, 26-32, and 34-36 were rejected under 35 U.S.C. § 102(e) as anticipated by U.S. Patent No. 6,168,922 to Harvey et al. ("Harvey et al. '922") as defined by A Akane et al., "Identification of the Heme Compound Copurified with Deoxyribonucleic Acid (DNA) from Bloodstains, a Major Inhibitor of Polymerase Chain Reaction (PCR) Amplification," Forensic Sci. 39: 362-372 (1994) ("Akane et al. (1994)"). Claims 1-3, 10, 12-19, 22, 26, 28-32, and 34-36 were also rejected under 35 U.S.C. § 102(a) as anticipated by Harvey et al. '922 as defined by Akane et al. (1994).

Claims 7 and 23 were rejected under 35 U.S.C. § 103(a) as being unpatentable for obviousness over Harvey et al. '922.

Claim 49 was rejected under 35 U.S.C. § 103(a) as being unpatentable for obviousness over Chung et al. (1996), Sigman et al. '167, or Harvey et al. '922 (in the alternative) each in view of Ahern, The Scientist 9: 1-5 (1995) ("Ahern (1995)").

Claims 37-47 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 21-24 of copending Application Serial No. 09/805,785 ("the '785 Application").

Claims 1-16 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8 of U.S. Patent No. 6,548,546 to Baker ("Baker '546").

Claims 17-36 and 48 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8 of Baker '546 in view of Sigman et al. '167.

Claim 49 was rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8 of Baker '546 in view of Ahern (1995).

Reexamination of the application as amended, reconsideration of the rejections, and allowance of the claims remaining for consideration are respectfully requested.

## I. AMENDMENTS TO THE APPLICATION

Entry of the amendments to the application is respectfully requested. As detailed below, these amendments introduce no new matter.

These amendments are being made solely for the purpose of placing the pending claims in better form. Specifically, these amendments are being made to obviate the informalities noted in Paragraph 2 of the Office Action, to obviate the objections under 37 C.F.R. § 1.75(c) noted in Paragraph 3 of the Office Action, and to obviate the claim rejections under the second paragraph of 35 U.S.C. § 112 for indefiniteness, and for no other reasons.

Specifically, the specification is amended to add sequence identifiers where appropriate in Table 1 and to replace brackets in chemical names with parentheses. The chemical species designated are not thereby changed. Corresponding amendments are made to the claims to replace brackets in chemical names.

The dependencies of claim 5 and other analogous claims are changed so that they depend from a claim that specifies a broader concentration range of reagent. This is done in order that the range recited in claim 5 and other similar claims is narrower than the range recited in the claims from which they depend.

Claims 14, 30, and 45 are amended so that they do not encompass zero concentrations of the additional reagent.

The dependency of claim 32 is corrected so that it depends from claim 31.

Claim 46 is amended so that it clear that the nucleic acid being referred to is the test nucleic acid.

Claim 48 is amended so that the recitation of amplification has antecedent basis.

This response is being filed in accordance with recently revised 37 C.F.R. § 1.121, as set forth in 68 F.R. 38611 (June 30, 2003). If the amendment is considered to be not in compliance with recently revised 37 C.F.R. § 1.121, the Examiner is respectfully requested to contact the undersigned at her earliest possible convenience.

Accordingly, entry of the amendments to the specification and claims is respectfully requested.

## II. THE OBJECTIONS TO THE SPECIFICATION

The specification was stated to contain sequence disclosures that were encompassed by the definitions for nucleotide sequences set forth in 37 C.F.R. § 1.821(a)(1) and (a)(2). It was stated that the application failed to comply with the requirements for 37 C.F.R. §§ 1.821-1.825. Sequence identifiers were not given, a

written copy of the sequence listing was not submitted, and a computer readable form of the sequence listing also had not been submitted.

In order to address these issues, a Sequence Listing is submitted in both a written copy and a computer readable form. The specification, namely Table 1, is amended to add appropriate sequence identifiers. The DNA sequences recited in Table 1, which are primers or probes, are not changed, and no new matter is added by these amendments. The written copy of the sequence listing and the computer readable form are the same.

Accordingly, the Examiner is respectfully requested to withdraw this objection to the specification.

## III. THE OBJECTIONS TO THE CLAIMS

### A. The Objections to Claims 2, 18, and 38 for Informalities

Claims 2, 18, and 38 were objected to for an informality: namely, the claims included brackets. The claims have been amended to remove brackets in the names of the chemical compounds recited therein and to replace the brackets by parentheses. The structure of the compounds designated does not change as the result of this correction.

Accordingly, the Examiner is respectfully requested to withdraw this objection to claims 2, 18, and 38.

### B. The Objections to Claims 14, 30, and 45

Claims 14, 30, and 45 were objected to under 37 C.F.R. § 1.75(a) as being of improper dependent form for failing to further limit the subject matter of a previous

claim. Specifically, these claims were stated to recite concentrations of the additional enzyme inactivating component that included zero. These claims have been amended to exclude zero concentration of the additional enzyme inactivating component.

Accordingly, the Examiner is respectfully requested to withdraw this objection to claims 14, 30, and 45.

## IV. THE REJECTIONS UNDER THE SECOND PARAGRAPH OF 35 U.S.C. § 112

Claims 5, 9, 14, 21, 25, 30, 32-35, 41, 44, and 46-48 were rejected under the second paragraph of 35 U.S.C. § 112 as indefinite. (Paragraph 5 of the Office Action does not mention claim 48, but the detailed discussion below recites claim 48. It is assumed that this rejection is applicable to claim 48. Clarification is requested).

It is believed that the amendments to these claims obviate these rejections.

Specifically, claims 5, 9, 21, 25, 41, and 44 were considered indefinite for their recitation of "at least about." It was not clear if the term was meant to indicate "about a certain concentration" or if this was to indicate a minimum but no maximum. To clarify these claims, their dependency has been changed. For example, claim 5 is now dependent from claim 4, which specifies a range of "about 0.001M to 0.1M." Accordingly, the recitation of "at least about 0.01M" in claim 5 must be read in conjunction with claim 4, so that this means "about 0.01M to 0.1M."

Claims 14, 30, and 45 were considered to recite concentrations of the additional enzyme inactivating component of zero. These claims have been amended to recite a concentration of the enzyme inactivating component of up to 5%, not reciting zero concentration.

Claim 32 was stated to lack sufficient antecedent basis for the recitation of "said bodily fluid" as the claim was dependent from claim 20. It was suggested that claim 32 should be dependent from claim 31. This amendment has been made.

Claim 46 was stated to lack sufficient antecedent basis for the term "said nucleic acid" because it was stated to be unclear if the term referred to the nucleic acid containing test sample or the target nucleic acid of claim 37. Claim 46 is amended to clarify that the nucleic acid referred to is the test nucleic acid.

Claim 48 was stated to lack sufficient antecedent basis for the term "said amplification" as no amplification was recited in claim 1. Claim 48 is amended to clarify that the molecular assay referred to in claim 1 is an amplification reaction.

Accordingly, the Examiner is respectfully requested to withdraw these rejections.

## V. THE REJECTIONS UNDER 35 U.S.C. § 102

### A. The Rejection of Claims 1-8, 14-15, 17-24, 30, 36-43, 45-46 and 48 Under § 102(b) as Anticipated by Chung et al. (1996)

Claims 1-8, 14-15, 17-24, 30, 36-43, 45-46, and 48 were rejected under 35 U.S.C. § 102(b) as anticipated by C.H. Chung et al., "An Improved Method for Isolating High Quality Polysaccharide-Free RNA from Tenacious Plant Tissues," Mol. & Cells 6: 108-111 (1996) ("Chung et al. (1996")).

This rejection is respectfully traversed.

With respect to claims 1-8 and 14-15, Chung et al. (1996) does not teach the suppression of interference by a masking agent. The claims specifically require this

result (see claim 1). There is no discussion of any of the masking agents contemplated in the present application. The extraction of RNA from samples of pulverized sesame or perilla oilseeds does not inherently involve freeing the RNA from masking agents of the type recited in the claims of the present application. The suppression of interference by a masking agent cannot be said to be inherent in the disclosure of Chung et al. (1996). Inherency cannot be established by probabilities or possibilities. Continental Can Co. USA v. Monsanto Co., 20 U.S.P.Q. 2d 1746 (Fed. Cir. 1991). To support an anticipation rejection based on inherency, as the rejection of claims 1-8 and 14-15 appears to be, the Examiner must provide factual and technical grounds establishing that the inherent feature necessarily flows from the teachings of the prior art. Ex parte Levy, 17 U.S.P.Q. 2d 1461, 1464 (Bd. Pat. Off. App. & Int'f 1990). This is lacking here.

With regard to claims 17-24, 30, and 36, there is no disclosure in Chung et al. (1996) of "suppressing the interference of a masking agent on a molecular assay of a nucleic acid-containing test sample" as required by these claims. The demonstration of "enhanced absorbance ratios" is not sufficient to show that interference from a masking agent has been suppressed. What is demonstrated by "enhanced absorbance ratios" is the freedom of the nucleic acid preparation from protein contamination, as the $A_{260}/A_{280}$ ratio of a nucleic acid preparation is roughly indicative of the degree of protein contamination of the nucleic acid preparation. This is well known in the art, as nucleic acids (both DNA and RNA) absorb ultraviolet light strongly with a peak at 260 nanometers, while proteins absorb ultraviolet light with a peak at 280 nanometers. However, the absorbance ratio is at best a crude indication of purity and cannot, by itself, be taken to indicate suppression of interference from a potential masking agent. Many masking agents are nonprotein and do not necessarily absorb ultraviolet light in the relevant wavelength, so they may still be present despite a relatively high $A_{260}/A_{280}$ ratio.

With regard to claims 37-43, 45-46, and 48, there is no teaching in Chung et al. (1996) of improving hybridization of nucleic acids. [The "signal response" of Figure 2 of Chung et al. (1996) cannot be said to relate to improved hybridization, and there is no basis for concluding from Chung et al. (1996) that the method of Chung et al.

(1996) actually improved the hybridization or improved the performance of Northern blotting, in which RNA is separated by electrophoresis and hybridized to labeled DNA. The demonstration of intact and functional cDNA does not necessarily and inevitably lead to the conclusion that hybridization has been improved.

Accordingly, the Examiner is respectfully requested to withdraw this rejection.

B. The Rejection of Claims 1-6, 8-9, 14-22, 24-25, 30-41, and 43-48 Under 35 U.S.C. § 102(b) as Anticipated by Sigman et al. '167

Claims 1-6, 8-9, 14-22, 24-25, 30-41, and 43-48 were rejected under 35 U.S.C. § 102(b) as anticipated by PCT Published Patent Application No. WO 93/03167 by Sigman et al. ("Sigman et al. '167").

This rejection is also respectfully traversed. The teachings of Sigman et al. '167 are directed to methods of isolating and preserving DNA, specifically DNA associated with parasites such as *Trypanosoma cruzi*.

With respect to claims 1-6, 8-9, 14-22, 24-25, and 30-36, Sigman et al. '167 does not disclose or suggest the suppression of interference by a masking agent or the improvement of a signal response in a molecular assay due to the suppression of interference by a masking agent. Sigman et al. '167 is actually directed to the use of conditions in which controlled cleavage of the highly catenated closed circular DNA of parasites such as *T. cruzi* can be accomplished. If there is suppression of interference by a masking agent or the improvement of a signal response in a molecular assay, it is strictly inadvertent and unintentional. It is well-established in patent law that unintended anticipation is not anticipation. Tilghman v. Proctor, 102 U.S. 707 (1881). If the work of Sigman et al. '167 creates suppression of interference by a masking agent or the improvement of a signal response in a molecular assay due to suppression of interference by a masking agent, it is unintended and is not inherent in the methods disclosed by

Sigman et al. '167. In other words, there is no teaching in Sigman et al. '167 of suppression of interference by a masking agent or improvement in a signal produced by a molecular assay. The term "molecular assay" must, in light of the specification of the present application, be read to mean a molecular assay in which sequence-specific recognition, either between two nucleic acids or between a nucleic acid and a protein, plays some role. The chemical cleavage optimized in Sigman et al. '167 is not encompassed by this definition.

Again, inherency cannot be established by probabilities or possibilities. Continental Can Co., 20 U.S.P.Q. 2d at 1746. Prevention of degradation by a nuclease cannot be equated with the suppression of interference with a masking agent. Most masking agents do not act to degrade the DNA.

With respect to claims 37-41 and 43-48, Sigman et al. '167 fails to teach or disclose improvement in hybridization. Again, Sigman et al. '167 is focused on methods by which the DNA is subject to chemical cleavage. There is no teaching in Sigman et al. of improvement in hybridization. Again, any anticipation would be unintended and accidental, and would not be inherent in the methods of Sigman et al. '167.

C. The Rejection of Claims 1-6, 8-9, 14-16, 37-41, and 43-47 Under 35 U.S.C. § 102(b) as Anticipated by Zhang '390

Claims 1-6, 8-9, 14-16, 37-41, and 43-47 were rejected under 35 U.S.C. § 102(b) as anticipated by PCT Published Patent Application No. WO 95/35390 by Zhang ("Zhang '390").

This rejection is also respectfully traversed. With respect to claims 1-6, 8-9, and 14-16, there is no teaching in Zhang '390 of suppressing interference by a masking agent. The removal of unbound proteins, nucleic acids, or probes that might interfere with subsequent steps cannot be equated with the removal of a masking agent. There is

absolutely no teaching or suggestion in Zhang '390 of the removal of a masking agent, as that term is defined in the specification.

With respect to claims 37-41 and 43-47, there is again no teaching in Zhang '390 of improvement in hybridization of nucleic acids. The preamble must be given patentable weight as it "gives life, meaning, and vitality to the claim" and makes clear what is to be accomplished by the method steps recited in the claim. "If the claim preamble, when read in the context of the entire claim, recites limitations of the claim, or, if the claim preamble is 'necessary to give life, meaning, and vitality' to the claim, then the claim preamble should be construed as if in the balance of the claim." Pitney Bowes, Inc. v. Hewlett-Packard Co., 51 U.SP.Q. 2d 1161, 1165-66 (Fed. Cir. 1999). In the absence of any teaching in Zhang '390 as to what needs to be done to accomplish the goal of the method recited in these claims, there is no basis for this rejection.

D. The Rejection of Claims 1-3, 6, 10-19, 22, 26-32, and 34-36 Under 35 U.S.C. § 102(e) as Anticipated by Harvey et al. '922 as Defined by Akane et al. (1994)

Claims 1-3, 6, 10-19, 22, 26-32, and 34-36 were rejected under 35 U.S.C. § 102(e) as anticipated by U.S. Patent No. 6,168,922 to Harvey et al. ("Harvey et al. '922") as defined by A Akane et al., "Identification of the Heme Compound Copurified with Deoxyribonucleic Acid (DNA) from Bloodstains, a Major Inhibitor of Polymerase Chain Reaction (PCR) Amplification," Forensic Sci. 39: 362-372 (1994) ("Akane et al. (1994)"). Claims 1-3, 10, 12-19, 22, 26, 28-32, and 34-36 were also rejected under 35 U.S.C. § 102(a) as anticipated by Harvey et al. '922 as defined by Akane et al. (1994).

This rejection is respectfully traversed.

In the first place, there is no basis for the position taken by the Office that the prior application, Application Serial No. 09/185,401 ("the '401 Application") does not provide support for the recitation of a "masking agent" in general. It is conceded that

the '401 Application does recite hemoglobin and methemoglobin, which are typical masking agents as that term is used in the present specification and claims. It is well understood that not all specific examples of a compound that has a particular activity or properties be recited in the specification for there to be support for a more general recitation of a compound having such activity or properties. In re Wright, 27 U.S.P.Q. 2d 1510, 1513 (Fed. Cir. 1993) ("Nothing more than objective enablement is required, and therefore it is irrelevant whether [a] teaching is provided through broad terminology or illustrative examples.") There is nothing in the properties of hemoglobin or methemoglobin that makes them unrepresentative examples of masking agents as that term is used in the present specification and claims.

Even if priority is not granted for the '401 Application with respect to the recitation of "a masking agent" in general, Harvey et al. does not teach the claimed invention because Harvey et al. '922 does not teach adding the required components to a "test sample" as that term is used in the specification and claims of the present application. The nucleic acid is applied to an absorbent such as a paper (e.g., claim 1 of Harvey et al. '922). An example is a cellulosic paper (column 3, lines 16-18). The nucleic acid must be released from the support to create a "test sample."

The fact that heme was known to inhibit PCR reactions, as taught by Akane et al. (1994), does not make Harvey et al. '922 an anticipatory reference. Akane et al. (1994) tentatively identified the inhibitory component as a heme-blood protein complex. However, Harvey et al. '922 does not teach or suggest the method of the invention in which specific reagents are required to be added to a test sample.

Accordingly, the Examiner is respectfully requested to withdraw this rejection.

## VI. THE REJECTIONS UNDER 35 U.S.C. § 103(a)

### A. The Rejection of Claims 7 and 23 Under 35 U.S.C. § 103(a) as Unpatentable Over Harvey et al. '922

Claims 7 and 23 were rejected under 35 U.S.C. § 103(a) as unpatentable for obviousness over Harvey et al. '922.

This rejection is respectfully traversed. The basis of this rejection is that it would have been obvious to use the device of Harvey et al. '922 treated with sodium perchlorate as a chelator enhancing component because Harvey et al. '922 teaches that sodium perchlorate is a chaotropic agent. Although it may have in fact been *prima facie* obvious to use the device of Harvey et al. '922 treated with sodium perchlorate, this still does not teach the method of the invention. All claim limitations must be considered in evaluating the non-obviousness of an invention in light of prior art. In re Fine, 5 U.S.P.Q. 2d 1596 (Fed. Cir. 1988). As indicated above, Harvey et al. '922 does not teach the use of these agents in a test sample. Therefore, even though one of ordinary skill in the art might know that sodium perchlorate is a chaotropic agent, the combination of that knowledge with the teachings of Harvey et al. '922 does not result in the claimed invention.

Accordingly, the Examiner is respectfully requested to withdraw this rejection.

### B. The Rejection of Claim 49 Under 35 U.S.C. § 103(a) as Unpatentable Over Chung et al. (1996) or Sigman et al. '167 or Harvey et al. '922 in View of Ahern et al. (1995)

Claim 49 was rejected under 35 U.S.C. § 103(a) as being unpatentable for obviousness over Chung et al. (1996), Sigman et al. '167, or Harvey et al. '922 (in the alternative) each in view of Ahern, The Scientist 9: 1-5 (1995) ("Ahern (1995)").

This rejection is respectfully traversed.

Ahern (1995) is cited for the recitation of a kit format. Ahern (1995) does not remedy the deficiencies of the primary references, Chung et al. (1996), Sigman et al. '167, or Harvey et al. '922, which fail to teach suppression of interference by a masking agent in a molecular assay, such as the polymerase chain reaction (PCR) assay. Accordingly, the combination of Ahern with one or more of the primary references fails to teach or suggest the claimed invention in its entirety. For purposes of assessing patentability of a claimed invention over one or more references in terms of nonobviousness, the invention must be viewed as a whole. Jones v. Hardy, 220 U.S.P.Q. 1021 (Fed. Cir. 1984).

Accordingly, the Examiner is respectfully requested to withdraw this rejection.

## VII. THE OBVIOUSNESS-TYPE DOUBLE PATENTING REJECTIONS

### A. The Rejection of Claims 37-47 Over Claims 21-24 of the Copending '785 Application

Claims 37-47 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 21-24 of copending Application Serial No. 09/805,785 ("the '785 Application").

This rejection is now moot as the '785 Application has been abandoned.

### B. The Rejection of Claims 1-16 Over Claims 1-8 of Baker '546

Claims 1-16 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8 of U.S. Patent No. 6,548,546 to Baker ("Baker '546").

This rejection is respectfully traversed, because claims 1-8 of Baker '546 do not recite a method of suppressing interference by a masking agent in a molecular assay. Preservation of a sample cannot necessarily be equated with suppression of interference by a masking agent. In the absence of any evidence that one of ordinary skill in the art would have equated the two, there can be no basis for an obviousness-type double patenting rejection over claims 1-8 of Baker '546. In re Kaplan, 229 U.S.P.Q. 678 (Fed. Cir. 1986); In re Longi, 225 U.S.P.Q. 651 (Fed. Cir. 1985).

C. The Rejection of Claims 17-36 and 48 Over Claims 1-8 of Baker '546 in View of Sigman et al. '167

Claims 17-36 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8 of Baker '546 in view of Sigman et al. '167.

This rejection is also respectfully traversed, essentially for the reasons stated above with regard to the rejections of claims 1-16 over Baker '546. The obviousness-type double-patenting rejection is considered to be analogous to a prior art rejection under 35 U.S.C. § 103, and there is no teaching of the methods of claim 17-36, even if Baker '546 and Sigman et al. '167 are combined. As demonstrated above, Sigman et al. '167 does not disclose or suggest the suppression of interference by a masking agent or the improvement of a signal response in a molecular assay due to the suppression of interference by a masking agent. Therefore, the combination of Baker '546 and Sigman et al. '167 does not result in the claimed invention, and there is no basis for this obviousness-type double patenting rejection.

D. The Rejection of Claim 49 Over Claims 1-8 of Baker '546 in View of Ahern (1995)

Claim 49 was rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8 of Baker '546 in view of Ahern (1995).

This rejection is also respectfully traversed, essentially for the reasons stated above with regard to the rejections of claims 1-16 over Baker '546 and with regard to the rejections of claims 17-36 over Baker '546 in view of Sigman et al. '167. The obviousness-type double-patenting rejection is again considered to be analogous to a prior art rejection under 35 U.S.C. § 103, and there is no teaching of the kit of claim 49, even if claims 1-8 of Baker '546 and Ahern (1995) are combined. Ahern (1995) is merely cited for the recitation of products in kit format and does not remedy the deficiencies of claims 1-8 of Baker '546 with respect to the failure to teach or suggest suppression of a masking agent.

If any issues remain, the Examiner is respectfully requested to telephone the undersigned at (858) 450-0099 x302.

Respectfully submitted,

Date: April 29, 2005

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